

K961335

Section 2 510(k) Summary and Certification

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Device Name : GEM® Premier Plus
Blood Gas and Electrolyte Analyzer

Predicate Device : GEM® Premier
Blood Gas and Electrolyte Analyzer

Description :

The GEM Premier Plus is a small (12" x 10" x 16.5") Blood Gas and Electrolyte Analyzer designed for use by non-laboratory medical personnel at the point of care. The device, along with its disposable reagent cartridge is capable of measuring pO₂, pCO₂, pH, Na⁺, K⁺, iCa⁺⁺ and hematocrit from a single 200uL blood sample in 104 seconds. The device will also calculate the following derived parameters - HCO₃, TCO₂, Base Excess, O₂ Sat. The system is self calibrating with all calibration solutions, sensors, pump tubing and waste bag contained within a disposable cartridge.

Intended Use :

The GEM Premier Plus is designed for use by health care professionals to rapidly analyze patient whole blood samples at the point of care, in a clinical setting.

Technological Characteristics vs. Predicate Device :

The measurement technology used in the GEM Premier Plus is identical to that used in the predicate device, the GEM Premier

Non Clinical Tests to Support Equivalence Determination

The GEM Premier has been tested and found to comply with UL 544 and IEC1010-1

Clinical Tests to Support Equivalence Determination

The GEM Premier Plus was tested at five clinical sites and compared to the predicate device, the GEM Premier. All tests were performed by health care professionals with limited training in the use of blood gas and electrolyte analyzers. Patient samples were run on both the GEM Premier Plus and the GEM Premier instruments.

Conclusions Drawn From Clinical Tests

The results from the clinical tests demonstrated that the GEM Premier Plus and the predicate device, the GEM Premier were substantially equivalent in performance.

The manufacturer states that the device is safe and effective for its intended use as a Critical Care Blood Gas and Electrolyte Analyzer when operated per the GEM Premier Plus labeling.
